

REMARKS

In response to the Office Action mailed May 15, 2009 ("the Office Action"), Applicant respectfully requests reconsideration and reexamination of this application, removal of the rejections outlined below, and the timely allowance of the pending claims.

Status of the Claims

Claims 13-22 were pending in the application. Claims 1-12 were cancelled previously. Accordingly, claims 13-22 remain for examination.

Rejection of Claims Under 35 U.S.C. § 103(a)

Claims 13-22 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over WIPO Publication 2000/72768 A1 to Fortin ("Fortin")¹ in view of U.S. Patent 5,375,823 to Navas ("Navas"). Office Action at p. 2. The Examiner contends that Fortin discloses each of the elements of the claims except "first and second dampening members coupled to the first and second ends (38,39) of the first and second rod members (35,36)." *Id.* The Examiner further alleges that Navas teaches a device disclosing the remaining claimed elements and that it "would have been obvious to one skilled in the art to modify the device taught by Fortin, by having a dampening member attached to the first and second ends (38, 39) of the first and second rod

¹ Throughout this Response, in reference to the content of French language WIPO Publication 2000/72768 A1, Applicant will cite to U.S. Patent 7,029,472 to Fortin, which was filed as the national stage entry of the international application associated with WIPO Publication 2000/72768 A1, and which Applicant believes to be an accurate English translation thereof.

members (35, 36) as is taught by Navas[.]” *Id.* at p. 3. Applicant respectfully disagrees with and traverses this rejection for at least the following reasons.

(1) Examiner Has Not Provided a Reason Why It Would Have Been Obvious to Combine a Damper Designed for Intervertebral Stabilization With a Device for Rib Distraction

The standard for determining obviousness is set forth in *Graham v. John Deere*, 383 U.S. 1, 148 U.S.P.Q. 459 (1996). The factual inquiries established by the Court in *Graham* are as follows:

- (A) Determining the scope and content of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and
- (D) Evaluating evidence of secondary considerations.

After resolving these factual inquiries, the key to supporting any rejection under section 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court instructs that “[t]o facilitate review, this analysis [of whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue] should be made explicit.” *KSR Int’l Co. v. Teleflex Inc., et al.*, 127 S. Ct. 1727, 1741, 82 U.S.P.Q.2d 1385, 1396 (2007) (citing *In re Kahn*, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, 1336 (Fed. Cir. 2006) (“[R]jections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”)); *see also* M.P.E.P. § 2141(III). Here, the

Examiner has not articulated a reason why it would have been obvious to use Navas's teachings directed to intervertebral stabilization to modify Fortin, which is directed to rib distraction. Thus, the proposed combination of Fortin and Navas fails to support a *prima facie* case of obviousness.

The Examiner asserts that it would have been obvious to combine the device taught by Fortin with the device taught by Navas, "because the dampening device can act as a shock absorber, aiding in the dampening of stresses and strains put on the device as movement occurs in the body of the patient." Office Action at p. 3. However, Fortin does not suggest that stress and strain on the disclosed device is a known problem or that there is a known need for reducing stress and strain on such devices. Moreover, the Examiner fails to identify any other evidence that this was a known problem or need associated with the Fortin device. Furthermore, even if a need for "dampening of the stresses and strains put on the [Fortin] device" existed, the Examiner has failed to identify a reason that one of ordinary skill in the art would use a damper designed for intervertebral stabilization to reduce stress and strain on a distraction device implanted between or across ribs and not directly anchored to a vertebrae.

Navas and Fortin are directed to engagement of different anatomical structures and treatment of different disorders. Navas is directed to "[a]n improved damper... in an intervertebral stabilization device." Navas at Abstract (emphasis added). Accordingly, Navas teaches an intervertebral stabilization damper that is designed for placement between two screws that are respectively anchored in two vertebrae. See *id.* at FIG. 4 and col. 3, ll. 36-38. The device is intended for "functioning in parallel and in the same manner as the disc separating the two vertebrae." *Id.* at col. 3, ll. 39-41. Thus, Navas

is directed to treatment of disorders associated with the intervertebral discs. Navas does not disclose, teach, or suggest its device for use in conjunction with a distraction device or a device for straightening the spine.

In contrast, Fortin is directed to “[a] distraction device enabling management of the evolving deformation of the trunk of a child during growth.” Fortin at Abstract. Fortin describes “a tensioning device that is placed between the ribs of a child whose growth is incomplete[.]” *Id.* at col. 1, ll. 6-7; see FIGS. 13 and 14. The device is configured to be periodically modified in order to adjust the spacing and/or check movement between the ribs as the child grows. *Id.* at col. 2, ll. 35-39. Accordingly, the Fortin device is directed to treatment of disorders involving deformations of the trunk of a child, such as scoliosis. Fortin discloses, teaches, or suggests neither the use of its distraction device in conjunction with an intervertebral stabilization device, nor the existence of a problem associated with such distraction devices for which an intervertebral stabilization damper would be helpful.

Thus, whereas Navas relates to devices implanted between vertebrae, Fortin describes devices configured for placement between or across ribs, and while Navas relates to intervertebral stabilization and treatment of disc disorders, Fortin relates to controlling the spacing of the ribs in order to treat deformations of the trunk. Consequently, the references themselves do not provide a reason for combining their respective elements. Further, the Examiner has not articulated a reason why it would have been obvious to use Navas’s teachings directed to invertebral stabilization to modify Fortin’s device for rib distraction. Therefore, the proposed combination of Fortin

and Navas fails to support a *prima facie* case of obviousness, and the section 103 rejection should be withdrawn.

(2) The Invention as a Whole Would Not Have Been Obvious to One of Ordinary Skill in the Art

"In determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." M.P.E.P. § 2141.02(I) (emphasis in original, citations omitted). Here, the claimed invention as a whole would not have been obvious because the elements in combination do not merely perform the function that each element performs separately. See M.P.E.P. § 2141(V)(B).

The claimed elements in combination can provide for straightening of spines having deformities encompassing the lumbar region, but none of the elements disclosed in Navas or Fortin separately are able to do so. The device of Navas merely includes elements for stabilization and dampening of stresses between vertebrae. The device of Fortin only provides for adjusting and controlling the spacing between ribs to treat deformations of the trunk of a child within the thoracic region of the patient's vertebral column, not for deformities encompassing the lumbar region. In contrast, the claimed elements, in combination, can provide for straightening of spinal deformities beyond the thoracic region, such as deformities encompassing the lumbar region. See Present Application at ¶¶ [0007] and [0008] (as numbered in U.S. Patent Publication 2007/0149909 A1). Thus, the claimed elements as a whole differ from a mere

combination of the functions of the devices disclosed by Navas and Fortin, and therefore, the claimed invention as a whole would not have been obvious. Accordingly, the section 103 rejection should be withdrawn.

Conclusion

In view of the foregoing remarks, Applicant submits that this claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the Examiner's reconsideration and reexamination of the application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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